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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,504	06/30/2003	Nicole Kennerknecht	7601/80525	4867

7590 05/13/2004

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EXAMINER	
GRASER, JENNIFER E	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 05/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,504	KENNERKNECHT ET AL.	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *6/30/03* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The current status of all nonprovisional parent applications referenced in the "Cross-Reference to Related Applications" on page 1, line 1, should be included, i.e, now U.S. Patent Serial No. 6,613,545.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 15-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is vague and indefinite because it appears to be a method for producing a polypeptide, not a single amino acid as recited in the claim. Clarification is requested.

Claims 15 and 16 is vague and indefinite because it is drawn to a method of recombinantly producing 'a branched-chain L-amino acid" yet does not disclose either the polynucleotide sequence encoding the amino acid or the amino acid sequence of the polypeptide to be produced. The mere recitation of a name, i.e., 'brnE gene' or 'brnF gene', to describe the invention is not sufficient to satisfy the Statute's requirement of adequately describing and setting forth the inventive concept. The claim should provide any structural properties, such as the nucleic acid sequence which encodes the amino acid, which would allow for one to identify the protein without ambiguity. While the specification can be used

to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed. Additionally, it is not the gene, but the coding region which is taught in the specification. The use of the term 'gene' is improper in the claim. The term 'gene' should be changed to 'polynucleotide'.

Claim 15 is also vague and indefinite because it appears to be drawn to a recombinant method of producing a protein which utilizes a transformed bacterium cell which contains an expression vector containing the desired sequence to be expressed; however, the claim is not written this way. The claim is incomplete for omitting essential steps, such omission amounting to a gap between the steps. First, it is unclear what is meant by "fermenting a bacterium in which the brnE gene or brnF gene is amplified'. Claim 16 which depends from claim 15 recites that the bacterium has been transformed with a vector for the expression of brnE, brnF or both. The invention does not appear to be a PCR method as the wording of claim 15 would suggest, but instead a recombinant method of producing a protein which includes over-expression of a desired polypeptide. The method should recite, for example, "A process for producing a branched chain L-amino acid comprising introducing in a bacterial host cell a recombinant expression which consists essentially of the polynucleotide sequence set forth in SEQ ID NO: 2 or 4 [or a recombinant expression vector comprising a nucleic acid insert encoding a protein consisting essentially of SEQ

ID NO: 3 or 5], cultivating the recombinant host cell in an appropriate culture medium under conditions sufficient for the production of the branched chain L-amino acid, and isolating said L-amino acid from the culture medium ".

Correction is required.

Claim 18 is vague and indefinite because it appears that "SEQ ID NO:3" should be changed to "SEQ ID NO:2" because SEQ ID NO:3 is a polypeptide not a polynucleotide.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 15-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "A process for producing a branched chain L-amino acid comprising introducing in a bacterial host cell a recombinant expression vector which consists essentially of the polynucleotide sequence set forth in SEQ ID NO: 1; 101-1176 of SEQ ID NO:1; 2 or 4 [or a recombinant expression vector comprising a nucleic acid insert encoding a protein consisting essentially of SEQ ID NO: 3 or 5 or 101—853 of SEQ ID NO:6 or 853-1176 of SEQ ID NO:6], cultivating the recombinant host cell in an appropriate culture medium under conditions sufficient for the production of the branched chain L-amino acid, and isolating said L-amino acid from the culture medium ", does not reasonably provide enablement for "[a] process for producing a branched chain L-amino acid, comprising: a) fermenting a bacterium in which the brnE gene or

brnF gene is amplified;b) allowing said L-amino acid to accumulate either in said bacterium or in the medium in which said bacterium is fermented; and c) isolating said L-amino acid." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification teaches methods for recombinantly producing the polypeptides set forth in SEQ ID Nos: 3, 5, 101-853 of SEQ ID NO:6 and 853-1176 of SEQ ID NO:6. The nucleic acid sequences which encode these polypeptides is also taught, i.e., the polynucleotide sequences set forth in SEQ ID NO: 1; 101-1176 of SEQ ID NO:1; 2 or 4. The specification fails to teach any other sequences, nor does it teach the full brnE or brnF *genes*. However, the coding sequences of these polypeptides is taught. Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 clearly states: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." That requirement has not been met in this specification with respect

to sequences other than those set forth in the sequence disclosure. The claims should be limited to the specific sequences which are taught in the specification because it would take undue experimentation for one of skill in the art to discover a completely new 'brnF' or 'brnE' polypeptide or nucleic acid encoding said polypeptide.

Claim Rejections - 35 USC § 112

6. Claims 15 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description in this case only sets forth methods for recombinantly producing the polypeptides set forth in SEQ ID Nos: 3, 5, 101-853 of SEQ ID NO:6 and 853-1176 of SEQ ID NO:6. The nucleic acid sequences which encode these polypeptides is also taught, i.e., the polynucleotide sequences set forth in SEQ ID NO: 1; 101-1176 of SEQ ID NO:1; 2 or 4. The specification fails to teach any other nucleic acid or polypeptide sequences, nor does it teach the full brnE or brnF *genes*. Therefore, the written description is not commensurate in scope with the claims.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now

claimed." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Reiger et al (Glossary of Genetics and Cytogenetics, Classical and Molecular, 4th Ed., Springer-Verlay, Berlin, 1976) clearly define alleles as one of two or more alternative forms of a gene occupying the same locus on a particular chromosome..... and differing from other alleles of that locus at one or more mutational sites (page 17). Thus, the structure of naturally occurring allelic sequences are not defined. With the exception of the SEQ ID Nos. set forth in the sequence disclosure, the skilled artisan cannot envision the detailed structure of the encompassed polynucleotides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Lts., 18 USPQ2d 1016.

Furthermore, In The Reagents of the University of California v. Eli Lilly (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an

adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

No disclosure, beyond the mere mention of allelic variants is made in the specification. This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Therefore only methods for recombinantly producing the polypeptides using expression vectors which consists essentially of the polynucleotide sequence set forth in SEQ ID NO: 1; 101-1176 of SEQ ID NO:1; 2 or 4 [or a recombinant expression vector comprising a nucleic acid insert encoding a protein consisting essentially of SEQ ID NO: 3 or 5 or 101—853 of SEQ ID NO:6 or 853-1176 of SEQ ID NO:6], but not the full breadth of the claims meets the written description provisions of 35 USC 112, first paragraph.

7. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is (703) 872-9306 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

J Graser 5/10/04

Jennifer Graser
Primary Examiner
Art Unit 1645